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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,847	11/28/2001	Carlo Dante Rizzuto	ENZ-001	3197

959 7590 09/07/2004

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EXAMINER	
SULLIVAN, DANIEL M	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 09/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/995,847	RIZZUTO ET AL.	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,7,8 and 10-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 7, 8 and 10-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a reply to the Paper filed 23 June 2004 in response to the Non-Final Office Action mailed 19 December 2003. Claims 4, 9 and 46-69 were withdrawn from consideration and claims 1-3, 5-8 and 10-45 were considered in the 19 December Office Action. Claims 1, 3-6, 9 and 46-69 were canceled and claims 2, 7, 8, 10-16, 18, 21, 23-27 and 32-40 were amended in the 23 June Paper. Claims 2, 7, 8 and 10-45 are pending and under consideration.

Response to Amendment

Rejection of claims 1, 3, 5 and 6 is rendered moot by cancellation of the claims.

Specification

Objection to disclosure as containing informalities is withdrawn in view of the amendments.

Claim Rejections - 35 USC § 112

Claims 2, 7, 8 and 10-45 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons of record and herein below in the response to arguments.

Claims 2, 7, 8 and 10-45 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a modular molecular clasp comprising a single chain antibody 1LMK or 1A14 comprising YFP and CFP effector molecules, does not reasonably

provide enablement for the broad scope of any molecular clasp comprising two single chain antibody domains together forming a molecular recognition element comprising a ligand binding site; any effector and any transducer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims for reasons of record and herein below in the response to arguments.

Rejection of claims 2, 7, 18, 19, 21-33, 35 and 40-45 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.

Claim Rejections - 35 USC § 102

Rejection of claims 8, 15, 18, 24-26, 28, 29, 32 and 38-45 as being anticipated by Tsien *et al.*; claims 24, 25, 31, 32, 38 and 39 as being anticipated by Benito *et al.*; claims 24-26, 28, 29, 32, 38-40 and 43-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Baird *et al.*; and claims 24-29 and 32 as being anticipated by Zaccolo *et al.* is withdrawn in view of the amendments to the claims such that they depend from claim 2. The art does not teach or suggest a modular molecular clasp comprising two single chain antibodies domains together forming a ligand-binding site.

New Grounds Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is indefinite in reciting, "said molecular recognition element is selected from...single chain T cell receptors or single chain MHC molecules." In claim 2, from which claim 16 depends, the molecular recognition element is provided by two single chain antibody domains. Thus, a molecular recognition element that is a single chain T cell receptor or single chain MHC molecule appears to be outside of the scope of the molecular recognition element recited in claim 2. Therefore, a molecular recognition element that is a single chain T cell receptor or single chain MHC molecule lacks antecedent basis.

Response to Arguments

Claims 2, 7, 8 and 10-45 were rejected under 35 U.S.C. 112, first paragraph, as lacking adequate written description for the claimed subject matter beyond the scope of the described embodiments set forth in Example 1 (*i.e.*, modular molecular clasp comprising a single chain antibody 1LMK or 1A14 comprising YFP and CFP effector molecules).

In response to the *prima facie* case of record, Applicant has amended the claims such that the molecular recognition element is formed by two single chain antibody domains. However,

the claims still broadly encompass any conglomeration of heterologous components including a pair of single chain antibodies providing a molecular recognition element capable of recognizing any ligand, any effector and any transducer, wherein the components are configured such that upon ligand binding to the recognition element the molecular clasp undergoes an allosteric alteration which produces a detectable change in an activity of the effector.

With regard to the grounds for the rejection, applicant first asserts, "the purpose of the written description requirement is mainly to ensure that there is no new matter introduced by Applicants during later prosecution efforts" (paragraph bridging pages 10-11). Applicant's position is based on discussion in *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111 regarding one aspect of the written description requirement (*i.e.*, guarding against the inventor's overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation) and the statement in MPEP 2163.03 that rejection of an original claim for lack of written description should be rare. However, the statement cited from the MPEP is clearly not a prohibition on rejecting an original claim and the fact that a statement of an invention is in an original claim does not necessarily end all inquiry as to the satisfaction of the written description requirement. See *Enzo Biochem Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609 (CA FC 2002) at 1616 ("[R]egardless whether the claim appears in the original specification and is thus supported by the specification as of the filing date, § 112, ¶ 1 is not necessarily met... If a purported description of an invention does not meet the requirements of the statute, the fact that it appears as an original claim or in the specification does not save it. A claim does not become more descriptive by its repetition, or its longevity."). Furthermore, in *Enzo,* the Court rejected *Enzo's* argument that the written description requirement for generic

claims is necessarily met as a matter of law because the claim language appears *in ipsis verbis* in the specification, stating, "[e]ven if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed. The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement" and "The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described" (at 1616).

As discussed in the previous Office Action, the instant invention requires that the components of the molecular clasp be structured such that allosteric alteration of the of the molecular clasp is facilitated by the transducer in response to ligand binding to said molecular recognition element, producing a detectable change in an activity of said effector. However, the allosteric properties of the vast majority of molecular recognition elements and transducers comprised within the molecular clasps of the claims are unknown and properly configuring a molecular clasp is complicated by the fact that the nature of the allosteric modification required to obtain a detectable change in activity of any given effector or set of effectors is distinct. Given the complex and unpredictable nature of the subject matter claimed, one skilled in the art could not possibly visualize or recognize the generic molecular clasp of the claims because, with the exception of the modular molecular clasp comprising a single chain antibody 1LMK or 1A14 comprising YFP and CFP effector molecules set forth in Example 1, the description fails to teach how the component parts can be assembled to provide the function recited in the claims.

Applicant further argues that a description of the structure of the claimed invention coupled with a functional characteristic is sufficient to satisfy the written description requirement and the disclosure need not provide a detailed mechanism of how an invention works.

First, it should be pointed out that the case law and section of the MPEP cited by applicant to support the later argument has to do with the requirements for actual reduction to practice, which is not at issue here at least because the instant application provides only constructive reduction to practice.

With regard to the former argument, as discussed in the previous Office Action, adequate written description requires that the disclosure of structure and function is "coupled with a known or disclosed correlation between function and structure" (second full paragraph on page 5). In the instant case, the specification describes the structure of various component parts that might be used to assemble a molecular clasp. However, the components themselves do not have the function of a molecular clasp and, with the exception of a molecular clasp comprising a single chain antibody 1LMK or 1A14 comprising YFP and CFP effector molecules, the specification fails to teach how the component parts are configured such that allosteric alteration of the molecular clasp is facilitated in response to ligand binding to the molecular recognition element, producing a detectable change in an activity of the effector. Also as discussed in the previous Office Action, the disclosure provides nothing to suggest that the computer models used to design the molecular clasp comprising a single chain antibody 1LMK or 1A14 comprising YFP and CFP effector molecules, which are based on the crystal structure of specific antibody-ligand complexes, can be generally extended such that they are representative of the full scope of the claimed genus. Thus, the specification fails to disclose the claimed invention such that the

nexus of the structure and function recited in the claim is apparent to one of ordinary skill in the art beyond the molecular clasps described in Example 1.

Applicant argues that the disclosure of random mutagenesis coupled with screening for desired function would provide a skilled artisan with a powerful tool to make many molecular clasps, without the need to inquire into how the generated molecular clasps work and states, "a detailed description of those random mutagenesis coupled with screening methods, which the instant application contains, are sufficient for the purpose of written description. However, as Applicant points out in subsequent remarks, the Courts have clearly found that the written description requirement is severable from the enablement requirement. Therefore, a description of a method by which a molecule might be discovered, even if it were considered enabling (*arguendo*), does not adequately describe the molecule itself. As stated in the previous Office Action, "[i]t is not sufficient to define a molecular clasp solely by its principal functional property because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any molecule with that property. Also, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material."

Next, Applicant cites a claim from US Patent No. 5,988,204 and urges that he was unable to find a disclosure in the specification as to how the functional language set forth in the claim is effectuated. This argument is not probative because each patent application must be examined on its own merits and the allowance of similar claims to others is immaterial to the allowability of the instant claims (see *In re Giolito*, 530 F.2d 397, 188 U.S.P.Q. 645 (C.C.P.A. 1976). Determination of whether a claim meets the written description requirement of 35 U.S.C. §112,

first paragraph, is fact specific and the facts upon which allowance of the cited claim are based are not of record in the present case.

As discussed above, Applicant urges that the written description requirement of 35 U.S.C. §112, first paragraph is severable from its enablement requirement, which is acknowledged. Applicant then contends that the standard applied by the Examiner in making the written description rejection is actually an enablement issue. However, as stated in the passage from the Office Action cited by Applicant, the complexity of the claimed invention, the requirement that the components be configured to work together in a specific useful fashion, the absence of working examples beyond those provided in the art, and the failure of the disclosure to set forth structural features that identify the broad scope of the claimed subject matter, "the skilled artisan could not possibly envision the full scope of the claimed molecular clasp" (first full paragraph on page 8; emphasis added). These statements are clearly directed to establishing why the disclosure fails to demonstrate possession of the claimed invention, which is the standard for written description.

Applicant argues that the facts of the instant case are distinct from those of *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997), which were cited in the Office Action because in *Fiers*, the applicants attempt to claim a DNA sequence based on a method that could lead to the isolation of that sequence, without knowing the chemical structure of the DNA claimed. However, as discussed in the previous Office Action and herein above, beyond the scope of a molecular clasp comprising a single chain antibody 1LMK or 1A14 comprising YFP and CFP effector molecules, the chemical structure of the claimed molecular clasp is also unknown. Reciting that a molecular

clasp has the structure of two single chain antibody domains together forming a molecular recognition element comprising a ligand binding site; an effector and a transducer linking conserved regions of the single chain antibody domains and suggesting various molecules that might be used in making the molecular clasp does not adequately describe the invention because the skilled artisan cannot envision molecules which have the recited structure and function of a molecular clasp such that they can be distinguished from those which have the recited structure but do not have the function.

In *Regents of the Univ. Calif. v. Eli Lilly & Co*, the court found that in claims to genetic material, generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not adequate written description of claimed genus, since it does not distinguish genus from others except by function, and does not specifically define any of genes that fall within its definition, or describe structural features commonly possessed by members of genus that distinguish them from others. The court found that a patent does not provide adequate written description of claims generically reciting cDNA encoding vertebrate insulin and mammalian insulin, even though it discloses rat insulin-encoding cDNA which is species within scope of generic claims, since cDNA is not defined or described by mere name "cDNA," even if accompanied by name of protein that it encodes. Similarly, the instant application discloses two species of the claimed invention that are predicted by a computer model to have the function of a molecular clasp. For reasons of record, however, the species disclosed fail to describe the structural features commonly possessed by members of the claimed genus of molecular clasps that distinguish them from other molecules having the same structural elements recited in the claims but not the function of a molecular clasps.

Applicant asserts that the instant claims are analogous to Example 9 of the "Revised Interim Written Description Guidelines Training Materials". However, as stated in the section quoted by Applicant, the decision in Example 9 is based on a finding that, "a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims" (page 14 of the 23 June Paper). In contrast, the molecular clasp of the instant claims is generic to species of extraordinary structural diversity. Both the transducer domain and the effector domain of the claimed invention are essentially unlimited in structure and, although the molecular recognition element is limited to being provided by a single chain antibody, there is no limit on the structure of the molecular recognition element itself (*i.e.*, the functional domain). Thus, a person of skill in the art would expect substantial variation among species within the scope of the claims.

Finally, Applicant urges that in the pending claims the MRE comprises a single chain antibody, the skeleton structure of which is well conserved, and although the effector is not limiting, the specification has described representative species of the effector molecule that could be adapted to use in the claimed invention and a detailed description of the transducers is also included in the specification. This argument is not persuasive because, for reasons of record, it is not sufficient to describe component parts that might or might not be functional in the claimed invention. As discussed in the paragraph bridging pages 12-13 of the previous Office Action, the allosteric change occurring upon binding of any given ligand to any single chain antibody is not generally predictive of the allosteric change occurring upon binding of a different ligand to a different single chain antibody, and the allosteric change required to obtain a detectable response from one effector molecule is not predictive of the allosteric change required to obtain a

detectable response from any other effector molecule. As the specification fails to disclose which single chain antibodies can be used in combination with which transducer to produce a detectable change in the activity of any given effector, the skilled artisan would not have recognized that Applicant was in possession of the full scope of the claimed invention at the time of filing.

Applicant's arguments have been fully considered but are not deemed persuasive either individually or as a whole; therefore, the claims stand rejected under 35 U.S.C. §112, first paragraph as lacking adequate written description.

Claims 2, 7, 8 and 10-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a modular molecular clasp comprising a single chain antibody 1LMK or 1A14 comprising YFP and CFP effector molecules, does not reasonably provide enablement for the broad scope of any molecular clasp comprising two single chain antibody domains together forming a molecular recognition element comprising a ligand binding site; any effector and any transducer.

In response to the *prima facie* case of record, Applicant argues that the rejection is largely based on a somewhat narrow stand point of biochemical protein engineering and should instead be based on the approach of random mutagenesis coupled with screening. Applicant provides an example of temperature sensitive mutations, which from a protein engineering point of view are unpredictable, yet can be identified by random mutagenesis coupled with screening for a protein having the desired temperature sensitive activity. Applicant asserts that by combining protein engineering with random mutagenesis, heterologous protein domains with distinct functions can

be linked together to generate novel functions in the new protein as a whole and such novel functions can be further optimized by random mutagenesis.

Applicant further argues that it is not necessary to be able to predict whether a specific ligand-antibody interaction could provide a useful change in effector function because the purpose of screening is to find out which ligand-antibody interaction can result in such a change.

Thus, Applicant appears to acknowledge that the teaching of how to make the claimed invention rests on a teaching that the operative embodiments can be identified by empirical experimentation.

Applicant then asserts that the actual screening required is not overly large in view of the relatively high level of skill in the art at the time of filing. While it is acknowledged that the relative level of skill is high, it is noted that the cited example of "pharmaceutical companies", or, in the case of the PubMed search for "temperature-sensitive", the entire biomedical community, significantly overestimates the capabilities of the ordinary skilled artisan. One of ordinary skill in the relevant art is a highly trained individual. The combined resources of a pharmaceutical company or the biomedical community is well above what is ordinary and what might be routine for a pharmaceutical company would not be routine for one of ordinary skill. Furthermore, it should be noted that counting the number of hits on a two-word phrase in a scientific database is not a valid criteria upon which to evaluate whether claims meet the enablement requirement. For example, a search of a physical science database for the two-word phrase "time machine" is also likely to return many hits. This is, however, irrelevant to patentability. Likewise, citing published examples of specific temperature sensitive mutants is not relevant to the question of whether the instant claimed invention, for which the art does not

provide a single example, is enabled over a broad scope. Instead, the relevant inquiries are those set forth in *In re Wands* and discussed in detail in the previous Office Action.

In assessing the amount of experimentation required to make the invention, Applicant asserts that to determine if individual embodiments within the scope of the claims are enabled, a skilled artisan need not try to make all embodiments within the scope. Applicant uses an analogy of a claim to a table and urges that enablement for the full scope of a table does not rest on the amount of experimentation required to make all embodiments within the scope of a table because, "[i]f almost all individual embodiments within the scope are enabled according to this standard, the full scope is enabled, even though the combined amount of experimentation for all embodiments might be 'undue'" (page 18).

Applicant's point is taken, however, the analogy fails because it rests on the premise that "almost all individual embodiments within the scope are enabled". In contrast, the previous Office Action cites Marvin *et al.* who teaches, "[d]evelopment of most biosensors involves identification of a naturally occurring macromolecules (such as enzymes or antibody) with the requires specificity, discovery of a suitable signal, and construction of a detector adapted to the properties of the macromolecule in question. Although effective biosensors have been developed in this way, each device is unique and requires substantial development time and optimization", Brennan *et al.* who teaches, construction of an artificial enzyme system that provides regulation of enzyme activity by binding a factor "presents a challenge; the surface of the enzyme must be modified to create a binding site for another protein, yet at the same time the catalytic activity of the enzyme must be maintained. In addition, the binding event must result in structural changes that alter the catalytic activity of the engineered enzyme" (left column on page 5783) and

Richards who teaches that the type of protein engineering required to make the full scope of the claimed invention is extremely unpredictable, as even minor modifications in protein structure can have dramatic effects on function. Given the complexity of the molecules claimed and the art recognized unpredictability in the requirements for operability, absent evidence to the contrary, the skilled artisan would expect that the vast majority of embodiments within the scope of the claim would be inoperative.

Although the presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled, the scope of the claim may still not be enabled where undue experimentation is involved in determining those embodiments that are operable (MPEP 2164.08(b)). The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984). In the instant case, given the scope of the claims and the high degree of unpredictability regarding which, if any, embodiments are operable, determining which embodiments that were conceived, but not yet made, would be inoperative or operative would clearly require undue experimentation.

Finally, Applicant alleges that the facts in the instant case are essentially no different from the facts in *In re Wands*, wherein the CAFC found that a claim directed to an immunoassay method utilizing an antibody to assay for a substance comprising hepatitis B-surface antigen (HBsAg) was enabled for the full scope of monoclonal high affinity IgM antibody having a binding affinity constant for HBsAg of at least 10^9 M^{-1}.

However, comparing the facts in *In re Wands* with the facts of the instant case according to the analysis set forth in *Wands*, reveals substantial differences between the two.

Nature of the invention and Breadth of the claims: In *Wands*, the claims are directed to a method of using an antibody, not the antibody itself, wherein the antibody is limited to binding a single antigen. In contrast, the instant claims are directed to any molecule comprising two single chain antibody domains together forming a molecular recognition element, wherein the molecular recognition element can recognize any molecule, any transducer and any effector configured such that binding of a molecule to the molecular recognition element produces a detectable change in an activity of said effector. Further, the molecular clasp of instant claims is not limited to having any specific use. Thus, the scope of the instant claims is more akin to claiming all antibodies capable of performing some unspecified useful function than it is to the antibody of *Wands,* which is limited to being specific for a single ligand (antigen) and capable of use in a narrowly defined assay.

State of the prior art and level of predictability in the art: In *Wands*, the relevant art recognizes that raising antibodies and producing monoclonal antibodies against specific antigens is well developed and highly predictable. In the instant case, the art teaches that engineering an operable modular molecular clasp as taught in the instant application is highly unpredictable (discussed in detail above and in the previous Office Action).

Amount of direction provided by the inventor and existence of working examples: In *Wands*, the inventor provided six working examples and a method of producing antibodies that was essentially 100% effective.

In the instant case, the specification provides general teachings related to making and screening libraries and saddles the skilled artisan with the burden of devising the particulars of making and screening each library of molecular clasps comprising each combination of every molecular recognition element, an effector and a transducer encompassed by the molecular clasp of the claims. The specification also provides an example of a method of designing a molecular clasp based on computer modeling of specific single chain antibodies having known crystal structure. However, there is no actual reduction to practice of the modeled example and the record does not contain a single actual working example of a modular molecular clasp having the structural limitations set forth in the instant claims.

Thus, relative to the instant claims, the claims at issue in *Wands* were very narrow, directed to a specific method of using an antibody having a narrowly defined function, were based on a well developed and highly predictable art and were supported with several working examples. Clearly there are tremendous differences between the claims at issue in *Wands* and in the instant case with respect to the criteria used by the Court in determining enablement. Thus, the decision in *Wands* cannot be taken as directly applicable to the facts in the instant case. Instead, a careful analysis of the facts in the instant case according to the criteria set forth in *Wands*, provided in the previous Office Action, leads to the conclusion that the claims are not enabled for the full scope of the protection sought.

Applicant's arguments have been fully considered but are not deemed persuasive either individually or as a whole. Therefore, the claims stand rejected under 35 U.S.C. §112, first paragraph, as lacking enablement for the full scope of the claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M Sullivan, Ph.D.
Examiner
Art Unit 1636

DAVID [illegible]
PRIMARY EXAMINER